LABEL IN PART: "10 cc. Vial Diluent for Chorionic Gonadotropin * * * Contains 0.5% Phenol" and "Chorionic Gonadotropin 5,000 I.U. * * * For Intramuscular Injection Only."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially less than 5,000 I.U. of chorionic gonadotropin potency per vial.

LIBELED: 11-7-57, N. Dist. Okla.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 5,000 I.U." was false and misleading.

DISPOSITION: 12-2-57. Default—destruction.

5570. Del-Caps. (F.D.C. No. 40851. S. No. 59-057 M.)

QUANTITY: 1 drum containing 21,000 capsules, 4 1,000-capsule btls., 8 500-capsule btls., and 18 100-capsule btls. at Philadelphia, Pa.

SHIPPED: 6-4-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Drum) "Del-Caps" 15 Timed Disintegration Capsule. Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6-10 hours * * * Delmar Pharmacal Corp."

RESULTS OF INVESTIGATION: The capsules in the btls. had been repackaged by the dealer from the above-mentioned bulk drum.

Examination showed that the article contained the labeled amount of dextro-amphetamine sulfate; that 68 percent of the dextro-amphetamine sulfate ingredient was released within the first 2 hours; and that the entire labeled amount of such ingredient was released within 5 hours.

LIBELED: 10-23-57, E. Dist. Pa.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess, namely, the capsules of the article failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the label of the article contained a false and misleading representation that the dextro-amphetamine sulfate ingredient of the article would be released at a uniform rate over a 6- to 10-hour period.

DISPOSITION: 11-25-57. Default—destruction.

5571. Pyrilamine maleate capsules. (F.D.C. No. 40905. S. No. 68-952 M.)

QUANTITY: 20 ctns. at Woodside, N.Y.

SHIPPED: 6-19-57, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: "1000 Capsules Timcaps Pyrilamine Maleate 75 Mg. Timed Disintegration Capsule Each Capsule Contains 75 Mg. Pyrilamine Maleate Released gradually and equivalent to 3 doses of 25 mg. over a period of approximately 8 hours * * * Control 6668 * * * Distributed by Henry Schein Woodside, L.I., N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article contained the labeled amount of pyrilamine maleate and that it released 86 percent of its pyrilamine maleate content within 2 hours and 94 percent in 6 hours.

LIBELED: 10-29-57, E. Dist. N.Y.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess, namely, the capsules of the article failed to disintegrate at a uniform rate over an 8-hour period; and 502(a)—the label statement "Timed Disintegration Capsule Each Capsule Contains 75 Mg. Pyrilamine Maleate Released gradually and equivalent to 3 doses of 25 mg. over a period of approximately 8 hours" was false and misleading as applied to a product which did not release the drug at a uniform rate over a period of 8 hours.

DISPOSITION: 12–2–57. Default—destruction.

5572. Gardophen. (F.D.C. No. 40927. S. No. 48–728 M.)

QUANTITY: 11 btls. at Chicago, Ill.

SHIPPED: 7–15–57, from Philadelphia, Pa., by Garde Drug Co.

LABEL IN PART: "One Gallon Garde Gardophen (Elixir Hyoscyamine Comp.) * * * Each 5 cc (1 teaspoonful) contains: Phenobarbital (¼ Gr.). . . . 16.20 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 118 percent of the labeled amount of phenobarbital.

LIBELED: 10–31–57, N. Dist. Ill.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented or purported to possess since it contained more than the labeled amount of phenobarbital; and 502(a)—the label statement "Each 5 cc (1 teaspoonful) contains: Phenobarbital (¼ Gr.). . . . 16.20 mg." was false and misleading.

DISPOSITION: 12–3–57. Default—destruction.

5573. Haltron capsules and Haloplex capsules. (F.D.C. No. 40622. S. Nos. 68–981/2 M.)

QUANTITY: 4 100-capsule btls. and 1 500-capsule btl. of *Haltron capsules* and 10 100-capsule btls. of *Haloplex capsules* at Jersey City, N.J.

SHIPPED: 6–6–57 and 6–18–57, from Brooklyn, N.Y., by Halsey Drug Co.

LABEL IN PART: "C–1010 Blue Cross * * * Haltron Capsules Whole Liver with Ferrous Sulfate" and "C–1011 Blue Cross * * * Capsules Haloplex (liver B–12 Iron and Vitamins)."

RESULTS OF INVESTIGATION: Analyses showed that the *Haltron capsules* contained less than 50 percent of the declared amount of thiamine chloride (vitamin B_1) and that the *Haloplex capsules* contained less than 50 percent of the declared amount of vitamin C (ascorbic acid).

LIBELED: 9–5–57, Dist. N.J.

CHARGE: 501(c)—the strength of the articles, when shipped, differed from that which they purported and were represented to possess, namely, (*Haltron capsules*) 1.0 mg. of thiamine chloride and (*Haloplex capsules*) 50 mg. of ascorbic acid; and 502(a)—the statements on the label of the *Haltron capsules* "Each Capsule Contains * * * Thiamin Chloride 1.0 mg." and on the label of the *Haloplex capsules* "Each Capsule Contains * * * Ascorbic Acid 50 mg." were false and misleading.

DISPOSITION: 10–14–57. Default—destruction.